PMA Monthly approvals from 1/1/2016 to 1/31/2016

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P080028	01/08/2016	PMAO - PMA Origi	STORZ MEDICAL DUOLITH SD1 SHOCK WAVE THERAPY	STORZ MEDICAL AG	APPROVAL FOR THE STORZ MEDICAL DUOLITH SD1 SHOCK WAVE THERAPY. THIS DEVICE IS INDICATED FOR EXTRACORPOREAL SHOCK WAVE TREATMENT OF HEEL PAIN DUE TO CHRONIC PROXIMAL PLANTAR FASCIITIS FOR PATIENTS OF AGE GREATER THAN 18 YEARS WITH A HISTORY OF FAILED ALTERNATIVE CONSERVATIVE THERAPIES FOR AT LEAST SIX MONTHS. CHRONIC PROXIMAL PLANTAR FASCIITIS IS DEFINED AS TRACTION DEGENERATION OF THE PLANTAR FASCIAL BAND AT THE ORIGIN ON THE MEDIAL CALCANEAL TUBEROSITY THAT HAS PERSISTED FOR SIX MONTHS OR MORE.
P150011	01/08/2016	PMAO - PMA Origi	PERCEVAL SUTURELESS HEART VALVE	LIVANOVA CANADA CORP.	Approval for the Perceval Sutureless Heart Valve. This device is indicated for the replacement of diseased, damaged, or malfunctioning native or prosthetic aortic valves.
P150027	01/23/2016	PMAO - PMA Origi	PD-L1 IHC NIVOLUMAB PHARMDX	DAKO NORTH AMERICA, INC.	APPROVAL FOR THE PD-L1 IHC 28-8 PHARMDX. THIS DEVICE IS INDICATED FOR THE FOLLOWING: PD-L1 IHC 28-8 PHARMDX IS A QUALITATIVE IMMUNOHISTOCHEMICAL ASSAY USING MONOCLONAL RABBIT ANTI-PD-L1, CLONE 28-8 INTENDED FOR USE IN THE DETECTION OF PD-L1 PROTEIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED (FFPE) NON-SQUAMOUS NON SMALL CELL LUNG CANCER (NSCLC) AND MELANOMA TISSUE USING ENVISION FLEX VISUALIZATION SYSTEM ON AUTOSTAINER LINK 48. PD-L1 PROTEIN EXPRESSION IS DEFINED AS THE PERCENTAGE OF TUMOR CELLS EXHIBITING POSITIVE MEMBRANE STAINING AT ANY INTENSITY. PD-L1 EXPRESSION AS DETECTED BY PD-L1 IHC PHARMDX IN NONSQUAMOUS NSCLC MAY BE ASSOCIATED WITH ENHANCED SURVIVAL FROM OPDIVO® (NIVOLUMAB). POSITIVE PD-L1 STATUS AS DETERMINED BY PD-L1 IHC 28-8 PHARMDX IN MELANOMA IS CORRELATED WITH THE MAGNITUDE OF THE TREATMENT EFFECT ON PROGRESSION-FREE SURVIVAL FROM OPDIVO®.

Total - 3

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N16837/S021	01/19/2016	R - Real-Time Proc	ARTEGRAFT COLLAGEN VASCULAR GRAFT	ARTEGRAFT, INC.	APPROVAL FOR INCLUDING A NON-ANTIGENIC STATEMENT IN THE INSTRUCTIONS FOR USE.
P880086/S267	01/30/2016	R - Real-Time Proc	ASSURITY AND ENDURITY CORE FAMILY OF PACEMAKERS	St. Jude Medical	APPROVAL FOR AN ALTERNATE HYBRID ASSEMBLY FOR USE IN THE DEVICES.
P890003/S339	01/19/2016	N - Normal 180 Day	CARELINK MONITOR , CARDIOSIGHT READER, CARELINK EXPRESS MONITOR	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	APPROVAL FOR THE VISIA AF AND VISIA AF MRI SINGLE-CHAMBER (VR) ICD DEVICES AND PROGRAMMER APPLICATION SOFTWARE MODEL SW035.
P890003/S343	01/13/2016	R - Real-Time Proc	MEDTRONIC CARELINK HOME MONITOR 2490C	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	APPROVAL FOR SOFTWARE MODIFICATIONS TO THE CARELINK HOME MONITOR 2490C.
P900033/S042	01/07/2016	P - Panel Track	INTEGRA(R) DERMAL REGENERATION TEMPLATE,INTEGRA(R) MESHED DERMAL REGENERATION TEMPLATE,OMNIGRAFT (TM) DERMAL REGENERATIO	INTEGRA LIFESCIENCES	APPROVAL FOR THE INTEGRA OMNIGRAFT DERMAL REGENERATION MATRIX (A.K.A. OMNIGRAFT) AND INTEGRA DERMAL REGENERATION TEMPLATE. INTEGRA OMNIGRAFT DERMAL REGENERATION MATRIX IS INDICATED FOR USE IN THE TREATMENT OF PARTIAL AND FULL-THICKNESS NEUROPATHIC DIABETIC FOOT ULCERS THAT ARE GREATER THAN SIX WEEKS IN DURATION, WITH NO CAPSULE, TENDON OR BONE EXPOSED, WHEN USED IN CONJUNCTION WITH STANDARD DIABETIC ULCER CARE AND INTEGRA DERMAL REGENERATION TEMPLATE IS INDICATED FOR THE POSTEXCISIONAL TREATMENT OF LIFE-THREATENING FULL-THICKNESS OR DEEP PARTIAL-THICKNESS THERMAL INJURIES WHERE SUFFICIENT AUTOGRAFT IS NOT AVAILABLE AT THE TIME OF EXCISION OR NOT DESIRABLE DUE TO THE PHYSIOLOGICAL CONDITION OF THE PATIENT; REPAIR OF SCAR CONTRACTURES WHEN OTHER THERAPIES HAVE FAILED OR WHEN DONOR SITES FOR REPAIR ARE NOT SUFFICIENT OR DESIRABLE DUE TO THE PHYSIOLOGICAL CONDITION OF THE PATIENT; AND TREATMENT OF PARTIAL AND FULL-THICKNESS NEUROPATHIC DIABETIC FOOT ULCERS THAT ARE GREATER THAN SIX WEEKS IN DURATION WITH NO CAPSULE, TENDON OR BONE EXPOSED, WHEN USED IN CONJUNCTION WITH STANDARD DIABETIC ULCER CARE.
P910071/S016	01/15/2016	R - Real-Time Proc	ADATO SIL-OL 5000 SILICONE OIL	BAUSCH & LOMB	APPROVAL FOR SHELF LIFE EXTENSION FOR THE ADATO® SIL-OL 5000 SILICONE OIL.
P920015/S155	01/05/2016	N - Normal 180 Day	SPRINT QUATTRO MODEL 6946M LEAD	MEDTRONIC INC.	APPROVAL FOR THE SPRINT QUATTRO MODEL 6946M LEAD.
P920015/S164	01/19/2016	N - Normal 180 Day	SPRINT QUATTRO SECURE S MRI SURESCAN LEAD, SPRINT QUATTRO SECURE MRI SURESCAN LEAD	MEDTRONIC INC.	APPROVAL FOR THE VISIA AF AND VISIA AF MRI SINGLE-CHAMBER (VR) ICD DEVICES AND PROGRAMMER APPLICATION SOFTWARE MODEL SW035.

P920015/S168	01/11/2016	R - Real-Time Proc	MEDTRONIC MODEL 5019 HV SPLITTER/ADAPTOR	MEDTRONIC	APPROVAL FOR THE NEXT GENERATION ANALYZER CABLE INTERFACE ACCESSORY.
P930016/S046	01/11/2016	R - Real-Time Proc	STAR EXCIMER LASER SYSTEM	AMO MANUFACTURING USA, LLC	APPROVAL FOR CHANGES TO THE FRONT PANEL ASSEMBLY OF THE STAR S4 IR SYSTEM WITH RELATED CHANGES AND MINOR UPDATES TO THE STAR S4 IR OPERATORS MANUAL.
P950037/S153	01/28/2016	Y - 135 Review Tra	SELOX SR 45,SELOX SR 53,SELOX SR 60,SELOX JT 45,SELOX JT 53,SELOX ST 53,SELOX ST 60,SETROX S 45,SETROX S 53,SETROX S 60,	BIOTRONIK, INC.	APPROVAL FOR AN ALTERNATIVE DRUG ELUTION METHOD FOR STEROID LEADS.
P950039/S034	01/11/2016	R - Real-Time Proc	THINPREP PROCESSORS	HOLOGIC, INC.	APPROVAL FOR SOFTWARE MODIFICATIONS TO THE THINPREP 5000 PROCESSOR.
P970021/S044	01/04/2016	R - Real-Time Proc	GYNECARE THERMACHOICE III UTERINE BALLOON THERAPY SYSTEM	ETHICON, INC.	APPROVAL FOR CHANGES TO THE GYNECARE THERMACHOICE III UBT LABELS, INSTRUCTIONS FOR USE, OPERATING MANUAL, AND PATIENT LABELING.
P980016/S551	01/19/2016	N - Normal 180 Day	VISIA AF VR , S VR, AFMRI VR SURESCAN, PROGRAMMER SOFTWARE, IMPLANTABLE CARDIOVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	APPROVAL FOR THE VISIA AF AND VISIA AF MRI SINGLE-CHAMBER (VR) ICD DEVICES AND PROGRAMMER APPLICATION SOFTWARE MODEL SW035.
P980016/S560	01/13/2016	R - Real-Time Proc	EVERA MRI ,EVERA, MARQUIS, SECURA, MAXIMO II, INTRINSIC, PROTECTA, PROTECTA XT, VIRTUOSO	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	APPROVAL FOR SOFTWARE MODIFICATIONS TO THE CARELINK HOME MONITOR 2490C.
P980022/S177	01/22/2016	R - Real-Time Proc	PARADIGM REAL-TIME INSULIN PUMP, PARADIGM REAL-TIME REVEL INSULIN PUMP	MEDTRONIC MINIMED	APPROVAL FOR THE ADDITION OF AN ANNEALING PROCESS AND CHEMICAL EXPOSURE DURABILITY TEST FOR THE SMOKE COLOR IN THE PARADIGM REAL-TIME INSULIN PUMPS (MMT-722, MMT-722K), PARADIGM REAL-TIME REVEL INSULIN PUMPS (MMT-753, MMT-753K) AND MINIMED 530G INSULIN PUMPS (MMT-751). THESE ARE COMPONENTS OF THE PARADIGM REAL-TIME AND PARADIGM REAL-TIME REVEL AND MINIMED 530G SYSTEMS, RESPECTIVELY.
P980022/S179	01/21/2016	Y - 135 Review Tra	PARADIGM REAL-TIME SYSTEM, PARADIGM REAL-TIME REVEL SYSTEM, MINILINK REAL-TIME SYSTEM, GUARDIAN REAL TIME SYSTEM	MEDTRONIC MINIMED	APPROVAL FOR THE ADDITION OF A NEW LEAK TESTER TO THE MANUFACTURING PROCESS OF THE PARADIGM® REAL-TIME FAMILY OF INSULIN PUMPS AND THE MINIMED 530G INSULIN PUMP AT MEDTRONIC PUERTO RICO OPERATIONS CO. (MPROC). THE PARADIGM® REAL-TIME FAMILY OF INSULIN PUMPS AND THE MINIMED 530G INSULIN PUMP ARE COMPONENTS OF THE PARADIGM REAL-TIME/REAL-TIME REVEL SYSTEMS AND THE MINIMED 530G SYSTEM, RESPECTIVELY.
P980023/S066	01/28/2016	Y - 135 Review Tra	PROTEGO SD 60/16,PROTEGO SD 65/16,PROTEGO SD 75/18,PROTEGO S 60,PROTEGO S 65,PROTEGO S 75,PROTEGO T 65,PROTEGO TD 65/16,	BIOTRONIK, INC.	APPROVAL FOR AN ALTERNATIVE DRUG ELUTION METHOD FOR STEROID LEADS.
P980044/S028	01/27/2016	N - Normal 180 Day	SUPARTZ FX	SEIKAGAKU CORP.	APPROVAL FOR RELOCATION OF MANUFACTURING PROCESSES FOR SUPARTZ FX TO A NEW FACILITY WITHIN THE MANUFACTURING PLANT FOR THE PRODUCT, AS WELL AS A CONCURRENT CHANGE TO THE CONTAINER CLOSURE SYSTEM FOR THE PRODUCT.

P000037/S044	01/06/2016	O - Normal 180 Day	ON-X PROSTHETIC HEART VALVE	MEDICAL CARBON RESEARCH INSTITUTE, LLC (MCRI)	APPROVAL OF THE FOLLOWING CHANGES TO THE POST-APPROVAL STUDY FOR THE DEVICE: CLARIFICATION ON THE FOLLOW-UP INTERVALS.
P000039/S051	01/08/2016	O - Normal 180 Day	AMPLATZER SEPTAL OCCLUDER	AGA MEDICAL CORP.	APPROVAL FOR THE ADDITION OF INFORMATION FROM THE POST-APPROVAL STUDY TO THE INSTRUCTIONS FOR USE.
P010030/S068	01/26/2016	R - Real-Time Proc	LIFEVEST WEARABLE DEFIBRILLATOR	ZOLL LIFECOR CORPORATION	APPROVAL FOR AN ALTERNATE GEL FIRE POWER SWITCH AND HIGHER CAPACITY SD CARD ON THE LIFEVEST MODEL 4000.
P010031/S521	01/13/2016	R - Real-Time Proc	BRAVA, BRAVA QUAD, CONCERTO, CONCERTO II, CONSULTA, MAXIMO II,PROTECTA, PROTECTA XT, VIVA QUAD, VIVA S, VIVA XT	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	APPROVAL FOR SOFTWARE MODIFICATIONS TO THE CARELINK HOME MONITOR 2490C.
P030047/S030	01/04/2016	Y - 135 Review Tra	CORDIS PRECISE NITINOL STENT SYSTEMS	CORDIS CORP.	APPROVAL FOR REPLACEMENT OF A RAW MATERIAL SUPPLIER.
P040020/S058	01/06/2016	R - Real-Time Proc	ACRYSOF IQ RESTORE +3.0D ADD POWER INTRAOCULAR LENS	ALCON LABORATORIES, INC.	APPROVAL FOR A DIOPTRIC POWER RANGE EXPANSION AND NEW METROLOGY INSTRUMENT FOR THE ACRYSOF® IQ RESTOR® INTRAOCULAR LENSES (IOLS).
P040024/S079	01/26/2016	N - Normal 180 Day	RESTYLANE/RESTYLANE-L/ PERLANE/ PERLANE-L , RESTYLANE SILK (INJECTABLE GELS)	GALDERMA LABORATORIES L.P	APPROVAL FOR A NEW SYRINGE CONTAINER CLOSURE SYSTEM FOR RESTYLANE®, RESTYLANE-L®, PERLANE®, PERLANE-L® AND RESTYLANE® SILK.
P040029/S002	01/29/2016	O - Normal 180 Day	JSZ ORTHOKERATOLOGY (OPRIFOCON A) CONTACT LENSES FOR OVERNIGHT WEAR	EUCLID SYSTEMS CORPORATION	APPROVAL FOR UPDATED LABELING REFLECTING LONG-TERM DATA FROM THE POST-APPROVAL STUDY.
P050023/S089	01/28/2016	Y - 135 Review Tra	COROX OTW 75 UP STEROID, COROX OTW 85 UP STEROID	BIOTRONIK, INC.	APPROVAL FOR AN ALTERNATIVE DRUG ELUTION METHOD FOR STEROID LEADS.
P050052/S081	01/20/2016	O - Normal 180 Day	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	APPROVAL OF THE FOLLOWING CHANGES TO THE POST-APPROVAL STUDY FOR THE DEVICE:REVISIONS TO THE PATIENT DIARY, ENROLLMENT FORM AND RADIOLOGY FORM.
P060037/S043	01/15/2016	S - Special CBE	ZIMMER NEXGEN LPS-FLEX MOBILE AND LPS MOBILE BEARING KNEE SYSTEM	ZIMMER, INC.	APPROVAL FOR THE ADDITION OF WARNINGS REGARDING USE OF THE DEVICE IN THE MAGNETIC RESONANCE (MR) ENVIRONMENT.
P060038/S026	01/13/2016	R - Real-Time Proc	MITROFLOW AORTIC PERICARDIAL HEART VALVE MODEL DL	LIVANOVA CANADA CORP.	APPROVAL FOR MINOR DESIGN MODIFICATIONS TO THE MITROFLOW AORTIC PERICARDIAL HEART VALVE MODEL DL, NAMELY THE ADDITION OF RADIOGRAPHIC MARKERS ON THE SEWING RING AND ADDITION OF VISIBLE MARKERS ON THE SEWING CUFF. THE DEVICE, AS MODIFIED, WILL BE MARKETED UNDER THE TRADE NAME CROWN PRT AORTIC PERICARDIAL HEART VALVE WITH PR TREATMENT AND IS INDICATED FOR THE REPLACEMENT OF DISEASED, DAMAGED, OR MALFUNCTIONING NATIVE OR PROSTHETIC AORTIC VALVES.
P060040/S047	01/11/2016	R - Real-Time Proc	THORATEC HEARTMATE II LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORP.	APPROVAL FOR DESIGN MODIFICATIONS TO THE 14 V LITHIUM-ION BATTERY.

P070008/S064	01/28/2016	Y - 135 Review Tra	CELERITY 2D 75, CELERITY 2D 85,CELERITY 3D 75, CELERITY 3D 85, CELERITY PILOT 75, CELERITY PILOT 85, COROX OTW-L 75-BP,	BIOTRONIK, INC.	APPROVAL FOR AN ALTERNATIVE DRUG ELUTION METHOD FOR STEROID LEADS.
P080009/S010	01/26/2016	R - Real-Time Proc	SEDASYS COMPUTER-ASSISTED PERSONALIZED SEDATION SYSTEM	ETHICON ENDO-SURGERY, INC.	APPROVAL FOR SOFTWARE CHANGES TO FIX ISSUES WITH WIRELESS PRINTING RELIABILITY.
P080012/S030	01/12/2016	R - Real-Time Proc	PROMETRA PROGRAMMABLE INFUSION PUMP SYSTEM	FLOWONIX MEDICAL, INC.	APPROVAL FOR UPDATING THE PROMETRA PROGRAMMABLE INFUSION PUMP SYSTEM SOFTWARE TO VERSION 1.03.2. THE SOFTWARE UPDATE CONSOLIDATES THE CONFIGURATION DEVICE SOFTWARE WITH THE CLINICIAN PROGRAMMER.
P090012/S006	01/12/2016	Y - 135 Review Tra	MELAFIND	MELA SCIENCES, INC.	APPROVAL FOR THE FOLLOWING CHANGES: 1) CHANGES TO THE TOLERANCES IN THE COMPUTER MOUNT AND SWITCH BRACKET; 2) RELOCATION OF MOUNTING HOLES ON THE COMPLEMENTARY METAL OXIDE SEMICONDUCTOR (CMOS) PRINTED CIRCUIT BOARD (PCB); 3) OPTIMIZATION OF POWER SUPPLY CAPACITORS AND ADDITION OF RESISTOR VALUES TO TEST SET; AND; 3) CHANGES TO COMPUTER LED INDICATOR AND ASSOCIATED WIRING.
P100022/S014	01/06/2016	N - Normal 180 Day	ZILVER PTX DRUG-ELUTING PERIPHERAL STENT	COOK MEDICAL INCORPORATED	APPROVAL FOR CHANGES TO THE DELIVERY SYSTEM OF THE DEVICE.
P100025/S010	01/27/2016	N - Normal 180 Day	BREATH TEK UBT FOR H.PYLORI KIT (BREATH TEK UBT KIT) AND PEDIATRIC UREA HYDROLYSIS RATE CALCULATION APPLICATION (PUHR-CA	OTSUKA AMERICA PHARMACEUTICAL, INC.	APPROVAL FOR LABELING CHANGES TO THE PACKAGE INSERT AND THE HOW TO GUIDE FOR THE BREATHTEK® UBT FOR H. PYLORI KIT (BREATHTEK UBT KIT) AND PEDIATRIC UREA HYDROLYSIS RATE CALCULATION APPLICATION (PUHR-CA).
P100047/S064	01/15/2016	O - Normal 180 Day	HEARTWARE LEFT VENTRICULAR ASSIST SYSTEM	HEARTWARE, INC.	APPROVAL OF THE FOLLOWING CHANGES TO THE POST-APPROVAL STUDY FOR THE DEVICE: MODIFIED RANKIN SCORE (MRS) VALIDATION PLAN.
P110002/S011	01/27/2016	N - Normal 180 Day	THE MOBI-C CERVICAL DISC PROSTHESIS	LDR SPINE USA	APPROVAL FOR LARGER MOBI-C® ENDPLATE FOOTPRINTS.
P120010/S054	01/22/2016	R - Real-Time Proc	MINIMED 530G INSULIN PUMP	MEDTRONIC INC.	APPROVAL FOR THE ADDITION OF AN ANNEALING PROCESS AND CHEMICAL EXPOSURE DURABILITY TEST FOR THE SMOKE COLOR IN THE PARADIGM REAL-TIME INSULIN PUMPS (MMT-722, MMT-722K), PARADIGM REAL-TIME REVEL INSULIN PUMPS (MMT-753, MMT-753K) AND MINIMED 530G INSULIN PUMPS (MMT-751). THESE ARE COMPONENTS OF THE PARADIGM REAL-TIME AND PARADIGM REAL-TIME REVEL AND MINIMED 530G SYSTEMS, RESPECTIVELY.

P120010/S064	01/21/2016	Y - 135 Review Tra	MINIMED 530G SYSTEM, MINILINK REAL-TIME SYSTEM	MEDTRONIC INC.	APPROVAL FOR THE ADDITION OF A NEW LEAK TESTER TO THE MANUFACTURING PROCESS OF THE PARADIGM® REAL-TIME FAMILY OF INSULIN PUMPS AND THE MINIMED 530G INSULIN PUMP AT MEDTRONIC PUERTO RICO OPERATIONS CO. (MPROC). THE PARADIGM® REAL-TIME FAMILY OF INSULIN PUMPS AND THE MINIMED 530G INSULIN PUMP ARE COMPONENTS OF THE PARADIGM REAL-TIME/REAL-TIME REVEL SYSTEMS AND THE MINIMED 530G SYSTEM, RESPECTIVELY.
P120010/S072	01/21/2016	Y - 135 Review Tra	ENLITE GLUCOSE SENSORS	MEDTRONIC INC.	APPROVAL OF AN ALTERNATE SUPPLIER OF GLUCOSE OXIDASE USED IN THE FABRICATION OF THE ENLITE GLUCOSE SENSOR THAT IS A COMPONENT OF THE MINIMED 530G SYSTEM.
P120020/S011	01/22/2016	O - Normal 180 Day	SUPERA PERIPHERAL STENT SYSTEM	ABBOTT VASCULAR	APPROVAL FOR A POST-APPROVAL STUDY PROTOCOL.
P130021/S018	01/25/2016	Y - 135 Review Tra	COREVALVE EVOLUT BIOPROSTHESIS, CORE VALVE BIOPROSTHESIS, ACCUTRAK DELIVERY CATHETER SYSTEM, GEN 3 & GEN4 COMPRESSION LO	MEDTRONIC COREVALVE LLC	APPROVAL FOR MODIFICATIONS TO THE ACCEPTANCE CRITERIA FOR THE PARAMETERS MEASURED BY THE MANUFACTURING FUNCTIONAL TESTER.
P130024/S006	01/29/2016	O - Normal 180 Day	LUTONIX 035 DRUG COATED BALLOON PTA CATHETER	LUTONIX	APPROVAL OF THE FOLLOWING CHANGES TO THE POST-APPROVAL STUDY FOR THE DEVICE: CHANGE IN STUDY DESIGN, PRIMARY EFFECTIVENESS COMPARATOR AND PRIMARY SAFETY COMPARATOR.
P140010/S012	01/06/2016	Y - 135 Review Tra	IN.PACT ADMIRAL PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC INC.	APPROVAL OF AN ALTERNATE BUILDING FOR THE END ITEM MANUFACTURING LINE AND ASSOCIATED WORKSTEPS.
P140011/S002	01/13/2016	S - Special CBE	MAMMOMAT INSPIRATION TOMOSYNTHESIS OPTION	SIEMENS MEDICAL SOLUTIONS USA, INC.	APPROVAL TO IMPLEMENT A SOFTWARE UPDATE THAT RESOLVES AN ERROR THAT MAY OCCUR DURING TOMOSYNTHESIS RECONSTRUCTION WITH A BREAST THICKNESS LARGER THAN 90 MM.
P140012/S001	01/14/2016	O - Normal 180 Day	RESHAPE INTEGRATED DUAL BALLOON SYSTEM	RESHAPE MEDICAL, INC.	APPROVAL OF THE POST-APPROVAL STUDY PROTOCOL.
P140012/S003	01/22/2016	R - Real-Time Proc	RESHAPE INTEGRATED DUAL BALLOON SYSTEM, RESHAPE BALLOON ASSEMBLY, RESHAPE REMOVAL CATHETER, RESHAPE VALVE SEALANT	RESHAPE MEDICAL, INC.	APPROVAL FOR A DIMENSIONAL CHANGE TO THE TORQUE TRANSMISSION WIRE COMPONENT OF THE RESHAPE REMOVAL CATHETER ASSEMBLY.
P140031/S003	01/26/2016	N - Normal 180 Day	SAPIEN 3 TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	APPROVAL FOR VARIOUS DESIGN AND MANUFACTURING CHANGES TO THE EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE, MODEL 9600TFX, INCLUDING CHANGE IN MATERIAL SPECIFICATION FOR THE POLYETHYLENE TEREPHTHALATE (PET) RIBBON, CHANGE IN SUTURE MATERIAL, AND REDUCTION IN THE NUMBER OF PERMANENT STITCHES.

Total: 51

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P790002/S034	01/14/2016	X - 30-Day Notice	BIOMET EBI BONE HEALING SYSTEM	EBI, LLC	QUALIFICATION OF AN ALTERNATE SUPPLIER TO PROVIDE ISOPROPYL ALCOHOL.
P790005/S054	01/14/2016	X - 30-Day Notice	EBI OSTEOGEN IMPLANTABLE BONE GROWTH STIMULATORS	EBI, LLC	QUALIFICATION OF AN ALTERNATE SUPPLIER TO PROVIDE ISOPROPYL ALCOHOL.
P810032/S064	01/06/2016	X - 30-Day Notice	PMMA MULTI-PIECE POSTERIOR CHAMBER INTRAOCULAR LENS	ALCON LABORATORIES	REQUESTED PARAMETRIC RELEASE FOR THE ALCON HUNTINGTON AODC NORTH (AODC-N) ETHYLENE OXIDE STERILIZATION PROCESS.
P830061/S125	01/13/2016	X - 30-Day Notice	CAPSURE SENSE LEAD, CAPSURE SP NOVUS LEAD, VITATRON CRYSTALLINE LEAD; VITATRON EXCELLENCE LEAD PS+LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	IMPLEMENTATION OF THE LEADS SERIAL NUMBER GENERATOR EQUIPMENT CONTROLLER VERSION 4.0.0.
P830061/S126	01/25/2016	X - 30-Day Notice	CAPSURE SENSE LEAD, CAPSURE SP LEAD, CAPSURE SP NOVUS LEAD, VITATRON CRYSTALLINE LEAD, VITATRON EXCELLENCE PS+LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	IMPLEMENTATION OF SELECT FINAL REPACKAGING MANUFACTURING ACTIVITIES AT MEDTRONIC'S MEMPHIS DISTRIBUTION CENTER IN MEMPHIS, TENNESSEE FOR THE DEVICES.
P840001/S319	01/22/2016	X - 30-Day Notice	RESTORE, ITREL AND SYNERGY SPINAL CORD STIMULATION SYSTEM AND PISCES, RESUME, SPECIFY, AND VECTRIS SPINAL CORD STIMULATI	MEDTRONIC INC.	THE TRANSFER OF RECEIVING AND INCOMING INSPECTION ACTIVITIES FOR DEVICE COMPONENTS USED IN THE MANUFACTURE OF MEDTRONIC NEUROMODULATION THERAPY DELIVERY PRODUCTS TO ALTERNATE FACILITIES.
P840001/S320	01/25/2016	X - 30-Day Notice	RESTORE,ITREL,AND SYNERGY SPINAL CORD STIMULATION SYSTEMS AND PISCES,RESUME,SPECIFY, AND VECTRIS SPINAL CORD STIMULATION	MEDTRONIC INC.	Acceptance for implementation of new performance software and re-packaging of selective returned products at Medtronics distribution center in Memphis, Tennessee.
P840060/S041	01/06/2016	X - 30-Day Notice	PMMA SINGLE-PIECE POSTERIOR CHAMBER INTRAOCULAR LENS	ALCON LABORATORIES	REQUESTED PARAMETRIC RELEASE FOR THE ALCON HUNTINGTON AODC NORTH (AODC-N) ETHYLENE OXIDE STERILIZATION PROCESS.

P840062/S054	01/26/2016	X - 30-Day Notice	COLLACOTE, COLLATAPE, COLLAPLUG ABSORBABLE COLLAGEN WOUND DRESSING FOR DENTAL SURGERY	COLLA-TEC, INC.	ADDITION OF THE KINEMATICA POLYTRON PT 2500E MIXER TO IMPROVE THE TEST METHOD OF DISPERSION SAMPLES PREPARATION TO PROVIDE HOMOGENOUS SAMPLING FOR PERCENT SOLIDS TESTING.
P850022/S027	01/14/2016	X - 30-Day Notice	BIOMET ORTHOPAK NON-INVASIVE BONE GROWTH STIMULATOR SYSTEM, BIOMET SPINALPAK NON-INVASIVE SPINE FUSION STIMULATOR SYSTEM	EBI, LLC	QUALIFICATION OF AN ALTERNATE SUPPLIER TO PROVIDE ISOPROPYL ALCOHOL.
P850035/S041	01/14/2016	X - 30-Day Notice	SPF IMPLANTABLE SPINAL FUSION STIMULATORS	EBI, LLC	QUALIFICATION OF AN ALTERNATE SUPPLIER TO PROVIDE ISOPROPYL ALCOHOL.
P850089/S115	01/13/2016	X - 30-Day Notice	CAPSURE SP NOVUS LEAD; CAPSURE Z NOVUS LEAD; VITATRON EXCELLENCE SS+LEAD; VITATRON IMPULSE II LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	IMPLEMENTATION OF THE LEADS SERIAL NUMBER GENERATOR EQUIPMENT CONTROLLER VERSION 4.0.0.
P850089/S116	01/25/2016	X - 30-Day Notice	CAPSURE SP NOVUS LEAD; CAPSURE SP Z LEAD, CAPSURE Z NOVUS LEAD, VITATRON IMPULSE II LEAD.	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	IMPLEMENTATION OF SELECT FINAL REPACKAGING MANUFACTURING ACTIVITIES AT MEDTRONIC'S MEMPHIS DISTRIBUTION CENTER IN MEMPHIS, TENNESSEE FOR THE DEVICES.
P860003/S082	01/21/2016	X - 30-Day Notice	THERAKOS CELLEX PHOTOPHERESIS SYSTEM PROCEDURAL KIT	THERAKOS, INC.	A CHANGE IN THE INSPECTION PROCESS FOR CELLEX PROCEDURAL KIT CARTONS PRIOR TO THEIR PLACEMENT IN THEIR SHIPPING PALLETS.
P860004/S244	01/08/2016	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM	MEDTRONIC INC.	CHANGE TO THE INCOMING INSPECTION METHODS FOR COIL INSULATION AND COIL RESISTANCE FOR THE MOTOR USED IN THE SYNCHROMED® II PUMP.
P870072/S061	01/21/2016	X - 30-Day Notice	THORATEC VENTRICULAR ASSIST DEVICE SYSTEM	THORATEC CORP.	REQUESTED A STERILIZATION CYCLE CHANGE FOR THE THORATEC VENTRICULAR ASSIST DEVICE SYSTEM.
P870076/S019	01/27/2016	X - 30-Day Notice	DISPOSABLE FALOPE-RING BAND APPLICATOR KITS	GYRUS ACMI, INC.	CHANGE IN SUPPLIERS FROM SENIOR OPERATIONS LLC (FORMERLY KNOWN AS GORMAC PRODUCTS) TO GYRUS ACMI NORWALK, OH FACILITY (ESTABLISHMENT REGISTRATION NUMBER 1519132) FOR THE MANUFACTURE OF THE FOLLOWING COMPONENTS OF YOUR DEVICE: FALOPE RING BAND APPLICATOR FORCEPS INNER TUBE (PART NUMBER 005261); OUTER TUBE (PART NUMBER 005262); AND CANNULA SLEEVE (PART NUMBER 004557-3).
P880086/S266	01/04/2016	X - 30-Day Notice	ASSURITY, ASSURITY+, ENDURITY, ENDURITY CORE FAMILY OF PACEMAKER DEVICES	St. Jude Medical	ALTERNATIVE SUPPLIER FOR THE TELEMETRY COIL COMPONENT OF THE HYBRID ASSEMBLIES.
P880087/S023	01/06/2016	X - 30-Day Notice	PMMA SINGLE-PIECE ANTERIOR CHAMBER INTRAOCULAR LENS	ALCON LABORATORIES	REQUESTED PARAMETRIC RELEASE FOR THE ALCON HUNTINGTON AODC NORTH (AODC-N) ETHYLENE OXIDE STERILIZATION PROCESS.
P890003/S347	01/13/2016	X - 30-Day Notice	CAPSURE VDD 2 LEAD; VITATRON BRILLIANT S +VDD LEAD;VITATRON BRILLAIANT S+VDD LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	IMPLEMENTATION OF THE LEADS SERIAL NUMBER GENERATOR EQUIPMENT CONTROLLER VERSION 4.0.0.

P890003/S348	01/25/2016	X - 30-Day Notice	CAPSURE VDD 2 LEAD. VITATRON BRILLIANT S+ VDD LEAD, VITATRON BRILLIANT S+VDD LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	IMPLEMENTATION OF SELECT FINAL REPACKAGING MANUFACTURING ACTIVITIES AT MEDTRONIC'S MEMPHIS DISTRIBUTION CENTER IN MEMPHIS, TENNESSEE FOR THE DEVICES.
P890023/S024	01/11/2016	X - 30-Day Notice	OCUFILCON D SOFT (HYDROPHILIC) CONTACT LENSES	THE COOPER COMPANIES	RELOCATION OF THE BIOMEDICS TORIC WET CELL, INSTALLATION OF A NEW TC20I UNIT IN THE BIOMEDICS TORIC QA STATION AND A SOFTWARE UPDATE FOR QA FINAL INSPECTION PRIOR TO MEASUREMENT OF TORIC LENSES.
P900061/S138	01/25/2016	X - 30-Day Notice	EPICARDIAL PATCH LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	IMPLEMENTATION OF SELECT FINAL REPACKAGING MANUFACTURING ACTIVITIES AT MEDTRONIC'S MEMPHIS DISTRIBUTION CENTER IN MEMPHIS, TENNESSEE FOR THE DEVICES.
P900061/S139	01/21/2016	X - 30-Day Notice	EPICARDIAL PATCH LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	REQUESTED UPDATES TO THE STAINLESS STEEL COMPONENT PASSIVATION PROCESSES FOR THE DEVICES.
P920015/S169	01/13/2016	X - 30-Day Notice	SPRINT QUATTRO LEAD, SUBCUTANEOUS LEAD; TRANSVENE CS/SVC LEAD	MEDTRONIC	IMPLEMENTATION OF THE LEADS SERIAL NUMBER GENERATOR EQUIPMENT CONTROLLER VERSION 4.0.0.
P920015/S170	01/25/2016	X - 30-Day Notice	SPRINT QUATTRO LEAD, SUBCUTANEOUS LEAD, TRANSVENE CS/SVC LEAD, HV SPLITTER/ADAPTOR KIT	MEDTRONIC	IMPLEMENTATION OF SELECT FINAL REPACKAGING MANUFACTURING ACTIVITIES AT MEDTRONIC'S MEMPHIS DISTRIBUTION CENTER IN MEMPHIS, TENNESSEE FOR THE DEVICES.
P930014/S088	01/06/2016	X - 30-Day Notice	ACRYSOF POSTERIOR CHAMBER INTRAOCULAR LENS	ALCON RESEARCH, LTD.	REQUESTED PARAMETRIC RELEASE FOR THE ALCON HUNTINGTON AODC NORTH (AODC-N) ETHYLENE OXIDE STERILIZATION PROCESS.
P930029/S054	01/21/2016	X - 30-Day Notice	RF MARINR 5F SC, RF MARINR 5F SCXL, RF MARINR 5F SCXS, RF MARINR 5F SCXXL	MEDTRONIC INC.	REQUESTED UPDATES TO THE STAINLESS STEEL COMPONENT PASSIVATION PROCESSES FOR THE ABOVE REFERENCED DEVICES.
P930039/S145	01/13/2016	X - 30-Day Notice	CAPSUREFIX LEAD; CAPSUREFIX NOVUS LEAD; SUREFIX LEAD;VITATRON CRYSTALLINE ACTIVE FIXATION LEAD; VITATRON CRYSTALLINE ACT	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	IMPLEMENTATION OF THE LEADS SERIAL NUMBER GENERATOR EQUIPMENT CONTROLLER VERSION 4.0.0.
P930039/S146	01/25/2016	X - 30-Day Notice	CAPSUREFIX LEAD. CAPSUREFIX NOVUS LEAD, SUREFIX LEAD, VITRATRON CRYSTALLINE ACTIVE FIXATION LEAD, VITATRON CRYSTALLINE	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	IMPLEMENTATION OF SELECT FINAL REPACKAGING MANUFACTURING ACTIVITIES AT MEDTRONIC'S MEMPHIS DISTRIBUTION CENTER IN MEMPHIS, TENNESSEE FOR THE DEVICES.

P930039/S147	01/21/2016	X - 30-Day Notice	CAPSUREFIX LEAD, CAPSUREFIX NOVUS LEAD, VITATRON CRYSTALLINE ACTIVE FIXATION LEAD, VITATRON CRYSTALLINE ACTIVE FIXATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	REQUESTED UPDATES TO THE STAINLESS STEEL COMPONENT PASSIVATION PROCESSES FOR THE DEVICES.
P950022/S090	01/08/2016	X - 30-Day Notice	OPTISURE FAMILY OF HIGH VOLTAGE LEADS	St. Jude Medical	IMPLEMENTATION OF UPDATED PRIMER APPLICATION INSTRUCTIONS AND UPDATES TO MANUFACTURING TOOL AIDS.
P950024/S066	01/13/2016	X - 30-Day Notice	CAPSURE EPICARDIAL PACING LEAD	MEDTRONIC INC.	IMPLEMENTATION OF THE LEADS SERIAL NUMBER GENERATOR EQUIPMENT CONTROLLER VERSION 4.0.0.
P950024/S067	01/25/2016	X - 30-Day Notice	CAPSURE EPICARDIAL PACING LEAD	MEDTRONIC INC.	IMPLEMENTATION OF SELECT FINAL REPACKAGING MANUFACTURING ACTIVITIES AT MEDTRONIC'S MEMPHIS DISTRIBUTION CENTER IN MEMPHIS, TENNESSEE FOR THE DEVICES.
P950034/S044	01/07/2016	X - 30-Day Notice	SEPRAFILM ADHESION BARRIER	GENZYME CORP.	ADDITIONAL SUPPLIER OF POLY(METHYL METHACRYLATE) (PMMA), PLASKOLITE, TO BE QUALIFIED FOR USE IN THE MANUFACTURE OF THE CASTING SHEETS PRODUCED BY AIN PLASTICS. THE CASTING SHEETS ARE IN TURN USED IN THE MANUFACTURE OF THE DEVICE (SEPRAFILM).
P950034/S045	01/14/2016	X - 30-Day Notice	SEPRAFILM ADHESION BARRIER	GENZYME CORP.	AN EXTENSION OF THE POST-DHT DRY HEAT TREATMENT MAXIMUM HOLD TIME FOR YOUR SEPRAFILM ADHESION BARRIER DEVICE.
P960009/S244	01/22/2016	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	THE TRANSFER OF RECEIVING AND INCOMING INSPECTION ACTIVITIES FOR DEVICE COMPONENTS USED IN THE MANUFACTURE OF MEDTRONIC NEUROMODULATION THERAPY DELIVERY PRODUCTS TO ALTERNATE FACILITIES.
P960009/S245	01/25/2016	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Acceptance for implementation of new performance software and re-packaging of selective returned products at Medtronics distribution center in Memphis, Tennessee.
P960028/S038	01/12/2016	X - 30-Day Notice	REZOOM 3-PC MULTIFOCAL	ABBOTT MEDICAL OPTICS INC	TO ADD 2 NEW CONTRACTORS TO PURIFY THE MONOMERS AND CROSS-LINKERS TO PRODUCE THE SILICONE MATERIAL USED IN THE ABOVE INTRAOCULAR LENSES.
P970004/S209	01/25/2016	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM	MEDTRONIC INC.	Acceptance for implementation of new performance software and re-packaging of selective returned products at Medtronics distribution center in Memphis, Tennessee.
P970051/S139	01/15/2016	X - 30-Day Notice	COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	ADDITION OF AN AUTOMATED MICROBLAST DEFLASHING OF THE FEEDTHROUGH FOR THE CI500 SERIES COCHLEAR IMPLANTS.
P980016/S564	01/25/2016	X - 30-Day Notice	EVERA MRI ICD, EVERA S DR ICD, EVERA S VR ICD. EVERA XT DR ICD, EVERA XT VR ICD, MAXIMO II ICD, PROTECTA ICD, PROTECTA X	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	IMPLEMENTATION OF SELECT FINAL REPACKAGING MANUFACTURING ACTIVITIES AT MEDTRONIC'S MEMPHIS DISTRIBUTION CENTER IN MEMPHIS, TENNESSEE FOR THE DEVICES.
P980035/S449	01/05/2016	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG	MEDTRONIC INC.	THE REMOVAL OF A SWAB TEST FOR THE ABOVE REFERENCED DEVICE.
P980035/S451	01/25/2016	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG, ADAPTA DR IPG, ADVISA DR MRI IPG, ADVISA DR MRI IPG, RELIA IPG,	MEDTRONIC INC.	IMPLEMENTATION OF SELECT FINAL REPACKAGING MANUFACTURING ACTIVITIES AT MEDTRONIC'S MEMPHIS DISTRIBUTION CENTER IN MEMPHIS, TENNESSEE FOR THE DEVICES.

P980040/S064	01/12/2016	X - 30-Day Notice	SENSAR 3PC & 1PC MONOFOCAL; TECNIS 1PC MONOFOCAL, 1PC MULTIFOCAL AND 1PC TORIC MONOFOCAL, 1PC OPTIBULE & 3PC OPTIBLUE	ABBOTT MEDICAL OPTICS INC	TO ADD 2 NEW CONTRACTORS TO PURIFY THE MONOMERS AND CROSS-LINKERS TO PRODUCE THE SILICONE MATERIAL USED IN THE ABOVE INTRAOCULAR LENSES.
P980044/S030	01/06/2016	X - 30-Day Notice	SUPARTZ FX	SEIKAGAKU CORP.	REQUESTED MODIFICATIONS TO EXISTING CLEANROOMS IN THE SUPARTZ FX MANUFACTURING FACILITY.
P980050/S102	01/13/2016	X - 30-Day Notice	TRANSVENE CS/SVC LEAD	MEDTRONIC INC.	IMPLEMENTATION OF THE LEADS SERIAL NUMBER GENERATOR EQUIPMENT CONTROLLER VERSION 4.0.0.
P980050/S103	01/25/2016	X - 30-Day Notice	TRANSVENE CS/SVC LEAD	MEDTRONIC INC.	IMPLEMENTATION OF SELECT FINAL REPACKAGING MANUFACTURING ACTIVITIES AT MEDTRONIC'S MEMPHIS DISTRIBUTION CENTER IN MEMPHIS, TENNESSEE FOR THE DEVICES.
P990075/S035	01/07/2016	X - 30-Day Notice	SPECTRUM BREAST IMPLANTS	MENTOR WORLDWIDE LLC	CHANGE TO THE SUPPLIER FOR THE FILL TUBE; A COMPONENT OF THE MENTOR SPECTRUM BREAST IMPLANTS.
P990080/S040	01/12/2016	X - 30-Day Notice	TENIS 3-PC MONOFOCAL-ZA9003	ABBOTT MEDICAL OPTICS INC	TO ADD 2 NEW CONTRACTORS TO PURIFY THE MONOMERS AND CROSS-LINKERS TO PRODUCE THE SILICONE MATERIAL USED IN THE ABOVE INTRAOCULAR LENSES.
P010015/S289	01/13/2016	X - 30-Day Notice	ATTAIN BIPOLAR OTW LEAD, ATTAIN OTW LV LEAD	MEDTRONIC INC.	IMPLEMENTATION OF THE LEADS SERIAL NUMBER GENERATOR EQUIPMENT CONTROLLER VERSION 4.0.0.
P010015/S290	01/25/2016	X - 30-Day Notice	ATTAIN BIPOLAR OTW LEAD, ATTAIN OTW LV LEAD, CONSULTA CRT-P, SYNCRA CRT-P, VIVA CRT-P	MEDTRONIC INC.	IMPLEMENTATION OF SELECT FINAL REPACKAGING MANUFACTURING ACTIVITIES AT MEDTRONIC'S MEMPHIS DISTRIBUTION CENTER IN MEMPHIS, TENNESSEE FOR THE DEVICES.
P010019/S043	01/15/2016	X - 30-Day Notice	LOTRAFILCON A & B SOFT CONTACT LENSES	ALCON LABORATORIES, INC.	THE IMPLEMENTATION OF AN ALTERNATE RAW MATERIAL SUPPLIER AND AN ANALYTICAL TEST METHOD.
P010031/S525	01/25/2016	X - 30-Day Notice	BRAVA CRT-D, BRAVA QUAD CRT-D, CONCERTO II CRT-D, CONSULTA CRT-D, MAXIMO II CRT-D, PROTECTA CRT-D , PROTECTA CRT-D, PROT	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	IMPLEMENTATION OF SELECT FINAL REPACKAGING MANUFACTURING ACTIVITIES AT MEDTRONIC'S MEMPHIS DISTRIBUTION CENTER IN MEMPHIS, TENNESSEE FOR THE DEVICES.
P010047/S042	01/26/2016	X - 30-Day Notice	PROGEL PLEURAL AIR LEAK SEALANT	NEOMEND, INC.	APPROVAL OF ALTERNATE SUPPLIERS OF TESTING REAGENTS USED FOR ANALYTICAL TESTING (I.E., THE BIURET TEST REAGENT AND PROTEIN PRIMARY STANDARD) OF THE TOTAL PROTEIN CONTENT OF THE HUMAN SERUM ALBUMIN (HAS) COMPONENT OF THE PROGEL PALS FINISHED DEVICE.
P020045/S070	01/12/2016	X - 30-Day Notice	FREEZOR CRYOABLATION CATHETERS, FREEZOR XTRA SURGICAL CRYOABLATION DEVICE, FREEZOR MAX SURGICAL CRYOABLATION DEVICE	MEDTRONIC CRYOCATH LP	ACCEPTANCE FOR A MODIFICATION TO A SUPPLIER'S MANUFACTURING EQUIPMENT.
P020045/S071	01/14/2016	X - 30-Day Notice	FREEZOR CARDIAC CRYOABLATION SYSTEM	MEDTRONIC CRYOCATH LP	ACCEPTANCE OF CHANGES PERFORMED DURING SUB-COOLER PERFORMANCE TESTING.

P020045/S072	01/27/2016	X - 30-Day Notice	FREEZOR CARDIAC CRYOABLATION SYSTEM	MEDTRONIC CRYOCATH LP	ACCEPTANCE FOR NEW ASSEMBLY AREA FOR REPLACEMENT PARTS THAT ARE USED FOR CONSOLE REPAIR AND SERVICING.
P030011/S037	01/07/2016	X - 30-Day Notice	SYNCARDIA TEMPORARY TOTAL ARTIFICIAL HEART (TAH-T) SYSTEM	SYNCARDIA SYSTEMS, INC.	CHANGE IN THE ASSEMBLER AND REPLACEMENT OF COMPONENTS FOR THE FREEDOM DRIVER MAIN PRINTED CIRCUIT BOARD ASSEMBLY.
P030017/S244	01/15/2016	X - 30-Day Notice	PRECISION SPECTRA SPINAL CORD STIMULATOR (SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	TO ADD AN ALTERNATE SUPPLIER FOR CERTAIN CAPACITORS USED IN THE PRECISION IPG'S PCBA.
P030022/S035	01/28/2016	X - 30-Day Notice	REFLECTION CERAMIC ACETABULAR HIP SYSTEM (RCHS)	SMITH & NEPHEW, INC.	LOCATION CHANGE OF A PACKAGE SUPPLIER.
P030035/S144	01/04/2016	X - 30-Day Notice	ALLURE AND ALLURE QUADRA FAMILY OF CRT-P DEVICES	St. Jude Medical	ALTERNATIVE SUPPLIER FOR THE TELEMETRY COIL COMPONENT OF THE HYBRID ASSEMBLIES.
P030036/S081	01/13/2016	X - 30-Day Notice	SELECTSECURE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	IMPLEMENTATION OF THE LEADS SERIAL NUMBER GENERATOR EQUIPMENT CONTROLLER VERSION 4.0.0.
P030036/S083	01/25/2016	X - 30-Day Notice	SELECTSECURE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	IMPLEMENTATION OF SELECT FINAL REPACKAGING MANUFACTURING ACTIVITIES AT MEDTRONIC'S MEMPHIS DISTRIBUTION CENTER IN MEMPHIS, TENNESSEE FOR THE DEVICES.
P030036/S084	01/21/2016	X - 30-Day Notice	SELECTSECURE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	REQUESTED UPDATES TO THE STAINLESS STEEL COMPONENT PASSIVATION PROCESSES FOR THE DEVICES.
P040005/S012	01/29/2016	X - 30-Day Notice	HER2 IQFISH PHARMDX	DAKO DENMARK A/S	CHANGE OF THE IN-PROCESS QC "METAPHASE FISH TEST', WITH CHANGE NUMBER R02285. PMA APPROVED DEVICES AFFECTED BY THE CHANGE ARE: HER2 CISH PHARMDX KIT AND HER2 IQFISH PHARMDX.
P040020/S059	01/06/2016	X - 30-Day Notice	ACRYSOF RESTOR POSTERIOR CHAMBER INTRAOCULAR LENS	ALCON LABORATORIES, INC.	REQUESTED PARAMETRIC RELEASE FOR THE ALCON HUNTINGTON AODC NORTH (AODC-N) ETHYLENE OXIDE STERILIZATION PROCESS.

P040027/S047	01/07/2016	X - 30-Day Notice	GORE VIATORR TIPS ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	REQUESTED AN ALTERNATE PTFE RESIN USED TO MANUFACTURE THE REINFORCING FILM COMPONENT.
P040033/S029	01/28/2016	X - 30-Day Notice	BIRMINGHAM HIP RESURFACING (BHR) SYSTEM	SMITH & NEPHEW, INC	LOCATION CHANGE OF A PACKAGE SUPPLIER.
P040033/S029	01/28/2016	X - 30-Day Notice	BIRMINGHAM HIP RESURFACING (BHR) SYSTEM	SMITH & NEPHEW, INC.	LOCATION CHANGE OF A PACKAGE SUPPLIER.
P040043/S079	01/08/2016	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	CHANGE IN THE MANUFACTURING PROCESSES OF THE GRAFT BASE TUBE COMPONENT.
P040044/S069	01/31/2016	X - 30-Day Notice	MYNX VASCULAR CLOSURE DEVICE PRODUCT FAMILY	ACCESS CLOSURE, INC.	TO SOURCE POLYETHYLENE GLYCOL (PEG) RAW MATERIALS USED IN THE HYDROGEL SEALANT OF MYNX DEVICES FROM AN ALTERNATE MANUFACTURING FACILITY.
P040045/S054	01/20/2016	X - 30-Day Notice	VISTAKON(SENOFILCON A) BRAND CONTACT LENSES	JOHNSON & JOHNSON VISION CARE, INC.	IMPLEMENTATION OF AN ALTERNATE CATALYST IN RAW MATERIAL PROCESS FOR A SENOFILCON A MONOMER COMPONENT OF VISTAKON (SENOFILCON A) BRAND CONTACT LENSES.
P050038/S028	01/07/2016	X - 30-Day Notice	ARISTA AH, ARISTA AH FLEXITIP/ FLEXITIP XL/ FLEXITIP XL-R	C.R. BARD, INC.	REQUESTED CHANGES IN THE SUPPLIER OF THE ARISTA AH FLEXITIP XL-R STAINLESS STEEL COMPONENT.
P060039/S068	01/13/2016	X - 30-Day Notice	ATTAIN STARFIX LEAD	MEDTRONIC INC.	IMPLEMENTATION OF THE LEADS SERIAL NUMBER GENERATOR EQUIPMENT CONTROLLER VERSION 4.0.0.
P060039/S069	01/25/2016	X - 30-Day Notice	ATTAIN STARFIX LEAD	MEDTRONIC INC.	IMPLEMENTATION OF SELECT FINAL REPACKAGING MANUFACTURING ACTIVITIES AT MEDTRONIC'S MEMPHIS DISTRIBUTION CENTER IN MEMPHIS, TENNESSEE FOR THE DEVICES.
P060040/S049	01/21/2016	X - 30-Day Notice	THORATEC HEARTMATE II VENTRICULAR ASSIST DEVICE (VAD) SYSTEM	THORATEC CORP.	REQUESTED A STERILIZATION CYCLE CHANGE FOR THE THORATEC HEARTMATE II VENTRICULAR ASSIST DEVICE SYSTEM.
P080006/S086	01/13/2016	X - 30-Day Notice	ATTAIN ABILITY LEAD, ATTAIN PERFORMA LEADS	MEDTRONIC INC.	IMPLEMENTATION OF THE LEADS SERIAL NUMBER GENERATOR EQUIPMENT CONTROLLER VERSION 4.0.0.
P080006/S087	01/25/2016	X - 30-Day Notice	ATTAIN ABILITY LEAD, ATTAIN PERFORMA LEAD, ATTAIN PERFORMA LEAD	MEDTRONIC INC.	IMPLEMENTATION OF SELECT FINAL REPACKAGING MANUFACTURING ACTIVITIES AT MEDTRONIC'S MEMPHIS DISTRIBUTION CENTER IN MEMPHIS, TENNESSEE FOR THE DEVICES.
P080010/S012	01/12/2016	X - 30-Day Notice	TECNIS 3PC MULTIFOCAL	ABBOTT MEDICAL OPTICS INC	TO ADD 2 NEW CONTRACTORS TO PURIFY THE MONOMERS AND CROSS-LINKERS TO PRODUCE THE SILICONE MATERIAL USED IN THE ABOVE INTRAOCULAR LENSES.
P080025/S104	01/25/2016	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM	MEDTRONIC INC.	Acceptance for implementation of new performance software and re-packaging of selective returned products at Medtronics distribution center in Memphis, Tennessee.
P090013/S212	01/13/2016	X - 30-Day Notice	CAPSUREFIX MRI LEAD	MEDTRONIC INC.	IMPLEMENTATION OF THE LEADS SERIAL NUMBER GENERATOR EQUIPMENT CONTROLLER VERSION 4.0.0.
P090013/S213	01/25/2016	X - 30-Day Notice	CAPSUREFIX MRI LEAD, REVO MRI SURESCAN IPG	MEDTRONIC INC.	IMPLEMENTATION OF SELECT FINAL REPACKAGING MANUFACTURING ACTIVITIES AT MEDTRONIC'S MEMPHIS DISTRIBUTION CENTER IN MEMPHIS, TENNESSEE FOR THE DEVICES.
P090013/S214	01/21/2016	X - 30-Day Notice	CAPSUREFIX MRI LEAD	MEDTRONIC INC.	REQUESTED UPDATES TO THE STAINLESS STEEL COMPONENT PASSIVATION PROCESSES FOR THE DEVICES.

P100010/S052	01/12/2016	X - 30-Day Notice	FREEZOR MAX CARDIAC CRYOBLATION CATHETERS	MEDTRONIC CRYOCATH LP	ACCEPTANCE FOR A MODIFICATION TO A SUPPLIER'S MANUFACTURING EQUIPMENT.
P100024/S008	01/29/2016	X - 30-Day Notice	HER2 CISH PHARMDX KIT	DAKO DENMARK A/S	CHANGE OF THE IN-PROCESS QC "METAPHASE FISH TEST', WITH CHANGE NUMBER R02285. PMA APPROVED DEVICES AFFECTED BY THE CHANGE ARE: HER2 CISH PHARMDX KIT AND HER2 IQFISH PHARMDX.
P100047/S071	01/15/2016	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	HEARTWARE, INC.	IMPLEMENTATION OF A NEW CLEANING AGENT AT ONE OF THE MACHINED PARTS SUPPLIERS.
P110002/S013	01/21/2016	X - 30-Day Notice	MOBI-C CERVICAL DISC PROSTHESIS	LDR SPINE USA	FOUR MANUFACTURING CHANGES, WHICH INCLUDED REPLACEMENT OF A WIRE CUTTING MACHINE, ADDITION OF NEW POLISHING STATIONS, UPDATES TO LASER MARKING MACHINES, AND THE ADDITION OF UPDATED TENSILE TESTING MACHINES.
P120005/S043	01/14/2016	X - 30-Day Notice	DEXCOM G4TM PLATINUM CONTINUOUS GLUCOSE MONITORING SYSTEM, DEXCOM G5 MOBILE CONTINIOUS GLUCOSE MONITORING SYSTEM	DEXCOM, INC.	ADDITION OF A CONTRACT STERILIZER FOR THE G5 MOBILE/G4 PLATINUM SENSOR. THE G5 MOBILE/ G4 PLATINUM SENSOR IS A COMPONENT OF THE DEXCOM G4 PLATINUM CONTINUOUS MONITORING SYSTEM AND THE DEXCOM G5 MOBILE CONTINUOUS GLUCOSE MONITORING SYSTEM.
P120005/S044	01/13/2016	X - 30-Day Notice	DEXCOM G4 PLATINUM CONTINUOUS MONITORING SYSTEM, DEXCOM G5 MOBILE CONTINUOUS GLUCOSE MONITORING SYSTEM	DEXCOM, INC.	TO ADD AN ADDITIONAL CONTRACT LABORATORY FOR PERFORMING BIOBURDEN AND STERILITY TESTING, WHICH IS USED TO SUPPORT OF STERILIZATION VALIDATION OF THE G5 MOBILE/G4 PLATINUM SENSOR. THE G5 MOBILE/G4 PLATINUM SENSOR IS A COMPONENT OF THE DEXCOM G4 PLATINUM AND THE DEXCOM G5 MOBILE CONTINUOUS GLUCOSE MONITORING SYSTEMS.
P120010/S081	01/14/2016	X - 30-Day Notice	ENLITE GLUCOSE SENSOR	MEDTRONIC INC.	ADDING AN ALTERNATE ENLITE SENSOR AUTOMATED HYBRID MANUFACTURING LINE (ENLITE AUTOMATION HYBRID LINE). THE ENLITE GLUCOSE SENSOR IS A COMPONENT OF THE MINIMED 530G SYSTEM.
P120010/S082	01/27/2016	X - 30-Day Notice	ARTIFICIAL PANCREAS DEVICE SYSTEM, THRESHOLD SUSPEND	MEDTRONIC INC.	THE APPROVAL OF A TRANSITION OF THE MANUFACTURING OF THE TYVEK LIDS USED FOR PACKAGING THE ENLITE SENSOR COMPONENT FROM THE SUPPLIER'S FACILITY IN PHILADELPHIA TO OSHKOSH, WISCONSIN. ADDITIONALLY, THE FACILITY TRANSITION INCLUDES NEW MANUFACTURING ASSETS INCLUDING COATER AND DIE CUT LID PRESS. THE ENLITE SENSOR IS A COMPONENT OF THE MINIMED 530G SYSTEMS.
P120017/S002	01/13/2016	X - 30-Day Notice	MYOCARDIAL PACING LEAD	MEDTRONIC INC.	IMPLEMENTATION OF THE LEADS SERIAL NUMBER GENERATOR EQUIPMENT CONTROLLER VERSION 4.0.0.
P120017/S003	01/25/2016	X - 30-Day Notice	MYOCARDIAL PACING LEAD	MEDTRONIC INC.	IMPLEMENTATION OF SELECT FINAL REPACKAGING MANUFACTURING ACTIVITIES AT MEDTRONIC'S MEMPHIS DISTRIBUTION CENTER IN MEMPHIS, TENNESSEE FOR THE DEVICES.
P130005/S010	01/21/2016	X - 30-Day Notice	DIAMONDBACK 360 CORONARY ORBITAL ATHERECTOMY DEVICE (OAD), ORBITAL ATHERECTOMY SYSTEM PUMP (OAS PUMP), VIPERWIRE ADVANCE	CARDIOVASCULAR SYSTEMS, INC.	A MANUFACTURING PROCESS CHANGE TO THE JOINING OF THE CROWN TO THE DRIVESHAFT OF THE OAS.
P130009/S044	01/08/2016	X - 30-Day Notice	NOVAFLEX+ DELIVERY SYSTEM, EDWARDS EXPANDABLE INTRODUCER SHEATH SET	EDWARDS LIFESCIENCES, LLC.	MODIFY THE RECEIVING VISUAL INSPECTION CRITERIA FOR THE POLYPROPYLENE TUBING USED FOR PACKAGING OF THE NOVAFLEX+ DELIVERY SYSTEM AND EDWARDS EXPANDABLE INTRODUCER SHEATH SET.
P140003/S007	01/25/2016	X - 30-Day Notice	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	TO ADD A SECOND SUPPLIER FOR THREE SUB-ASSEMBLIES USED TO BUILD THE FINAL IMPELLA PURGE CASSETTE.

P140015/S007	01/28/2016	X - 30-Day Notice	T:SLIM G4 INSULIN PUMP WITH DEXCOM G4 PLATINUM CGM	TANDEM DIABETES CARE, INC.	CHANGES TO THE PACKAGING VERIFICATION PROCESSES TO REPLACE 100% VISUAL INSPECTION WITH 100% PACKAGE CONTENTS VERIFICATION USING VALIDATED CHECKWEIGHT SCALE, AND CHANGES TO THE LABELING VERIFICATION PROCESS TO REPLACE 100% VISUAL VERIFICATION WITH ONCE-DAILY VISUAL INSPECTION OF A RETAINED LABEL FOR THE T:SLIM G4 INSULIN PUMP WITH DEXCOM G4 PLATINUM CGM SYSTEM.
P140015/S008	01/22/2016	X - 30-Day Notice	T:SLIM G4 INSULIN PUMP WITH DEXCON G4 PLATINUM CGM	TANDEM DIABETES CARE, INC.	TO MODIFY THE GEARBOX RUN-IN PRODUCTION PROCESS STEP TO INCLUDE THE USE OF PRODUCTION MOTORS RATHER THAN TEST MOTORS.
P140031/S004	01/04/2016	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE (26MM SIZE ONLY)	EDWARDS LIFESCIENCES, LLC.	ADD A NEW LASER FOR THE PRODUCTION OF THE 26 MM SAPIEN 3 TRANSCATHETER HEART VALVE FRAMES.
P140031/S005	01/04/2016	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	MANUFACTURING LINE CHANGE AND THE USE OF AMMONIUM PERFLUOROOCTANOATE (APFO) FREE RESIN.

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